

### **REMARKS**

Receipt of the office action mailed March 3, 2009 is acknowledged. Claims 1-25 are pending in the application. The Examiner has objected to the title, requiring a new title that is more indicative of the invention to which the claims are directed. Claim 13 is objected to because of an informality. Claims 1-25 are rejected under 35 U.S.C. §101 because the claimed invention allegedly is directed to non-statutory matter and because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility. Claims 1-25 are rejected under 35 U.S.C. §112 for failing to comply with the enablement requirement. Claims 1-25 are also rejected under 35 U.S.C. §112 as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. Claims 1-10 and 15-25 are rejected under 35 U.S.C. §102(a) as being anticipated by WO 02/38045 (“Charles.”) Claims 9-14, 16 and 23 are rejected under 35 U.S.C. §103(a) as being unpatentable over Charles as applied to claims 1 and 19 above, and further in view of Mitton et al., “3D Reconstruction Method from Biplanar Radiography Using Non-stereocorresponding Points and Elastic Deformable Meshes,” (“Mitton.”)

In keeping with the foregoing amendments and the following argument, reconsideration of the rejected claims is respectfully requested.

#### **Claim Objections**

The action objects to claim 13 because of informalities. The present amendment is believed to overcome this objection.

#### **Claim rejection under 35 USC §101**

##### **1) Utility under 35 USC §101**

Claims 1 to 25 are rejected under 35 USC §101 as allegedly not having utility. The examiner improperly asserts the claims do not have utility. The specification states the utility of the claims. The originally filed application specification at least at the summary section states the utility of the invention as follows:

By virtue of these provisions, it is possible to obtain, with a very limited number of images, that is to say with a relatively low level of irradiation, an index which takes account of the

three-dimensional shape of the osseous body examined. It is thus possible to ascertain the distribution in volume of this index, which can be especially representative of the bone mineral density. The method according to an embodiment of the invention thus provides, with a relatively low level of irradiation, a useful clinical index for evaluating the fracture risks and/or bone diseases and/or their treatment. The method according to an embodiment of the invention makes it possible not only to increase the precision of the measurements of the bone mineral density, but also to establish the macro-architecture of the osseous body analyzed. With a knowledge of the macro-architecture, it is possible, by taking into consideration various parameters of the bone mineral density alone, to refine the diagnosis of certain pathologies and of osteoporosis in particular.<sup>1</sup>

The claimed composite index is determined using digitized radiological data and a 3-dimensional generic model of an osseous body and is, therefore, a composite index of digitized radiological data and 3-dimensional geometry of an osseous body. The composite index is configured to take account of the three-dimensional shape of the osseous body to ascertain the distribution in volume of this index. (Application, page 2, lines 26-34.) Such composite index could be used, for example, to access the risk of bone fracture, and is therefore useful.

The PTO has the initial burden of challenging a presumptively correct assertion of utility in the disclosure. Only after the PTO provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to prove utility.<sup>2</sup>

## **2) Patentable Subject Matter under 35 USC §101**

Additionally, claims 1-18, 24, and 25 were rejected under 35 USC §101 for allegedly not describing patentable subject matter. Independent claim 1 has been amended to have the method claim tied to a particular machine (i.e., a processor of a radiographic image display

---

<sup>1</sup> Application Specification, page 2, line 26 to page 3, line 7.

<sup>2</sup> In re Brana, 51 F.3d 1560, 1566 (Fed. Cir. 1995.), and MPEP 2107 stating “(1) If the applicant has asserted that the claimed invention is useful for any particular practical purpose (i.e., it has a "specific and substantial utility") and the assertion would be considered credible by a person of ordinary skill in the art, do not impose a rejection based on lack of utility.”

device ) as required by the most recent 101 case law.<sup>3</sup> Support for this amendment is found in the originally filed application specification at least at Fig. 1 and page 15, lines 11-26. Therefore, withdrawal of this rejection is respectfully requested.

Claim 25 has been amended to recite a *computer program product of manufacture* that falls under the scope of a *Beauregard* claim, which has been established as a claim that recites patentable subject matter according to the USPTO Board of Patent Appeals and Interferences decision in *Ex Parte Bo Li*.<sup>4</sup> The examiner appears to reject claim 25 for its language, “a **support** readable by a computer.” Claim 25 is amended to recite, a “computer program *product of manufacture that includes a computer readable medium having a sequence of instructions which, when executed by a processor of a radiographic image display device, causes the processor of the radiographic image display device to execute the process* for digital processing of radiographic images” so that this objection is now moot. Therefore, withdrawal of this rejection is respectfully requested.

#### Claim rejections under 35 USC §112

Claims 1 to 25 stand rejected under 35 USC §112, first paragraph, as failing to comply with the enablement requirement.

However, the claimed subject matter is described in the specification. An example of calculation of a composite index or image is given at page 23, lines 26-36 of the PCT application as published. A patent need not teach and preferably omits, what is well known in the art.<sup>5</sup> One of ordinary skill in the art understands that an x-ray imaging device would capture and produce signals which would be introduced to the claimed radiographic image display device to produce an image that may be used to refine the diagnosis of certain pathologies, such as osteoporosis.

Claims 1 to 25 also stand rejected under 35 USC §112, first paragraph for reasons set forth above. However, as explained above in the 101 discussion, claims 1 to 25 are useful.

---

<sup>3</sup> See *In re Bilski*, 545 F.3d 943, 88 U.S.P.Q.2d 1385 (Fed. Cir. 2008.)

<sup>4</sup> See *Ex parte Bo Li*, Appeal 2008-1213 (BPAI 2008.)

<sup>5</sup> See *Hybritech v. Monoclonal Antibodies, Inc.* 802 F.2d 1367, 1384 (Fed. Cir. 1986.)

Claim 16 stands rejected under 35 USC §112 for using the phrase “and/or.” However, corresponding embodiments are given in a detailed description, page 25, lines 5 to 9 on the PCT application as published.

Claims 1, 19 and 24 stand rejected under 35 USC §112 for including the limitations “referred to a surface area unit.” This is part of the feature “the bone mineral density of the osseous body, referred to a surface area unit.” Indeed, the bone mineral density is calculated per unit of surface area. This is clear to one person skilled in the art (see for example, in Charles paragraph 87, “in units of mass per unit area.”) For clarity, claims 1, 19, and 24 are amended to recite “in units of a surface area unit.”

Claim 22 stands rejected under 35 USC §112 because of the limitation “a line of detection cells perpendicular to the axis of translation.” As seen, for example in Fig. 7, the detector cells 6 extend along a line which is in the plane of Fig. 7. Other detection cells 6' extend in a line which is also in the plane of Fig. 7. The axis of translation, in Fig. 7, is transverse to the plane of Fig. 7 and is perpendicular to lines 6, 6' of detection cells. The same applies to the other described embodiments. Hence, it is requested that this rejection of claim 22 be withdrawn.

Claims 1, 3 to 18 and 25 stand rejected because of the recitation of “(d)” and “(e).” The present claim amendments are believed to respond to this objection.

Claims 1, 2, 3, 9 to 13, 15 to 20 and 23 to 25 stand rejected for being indefinite for referring to “first” incidence and “first” image. The currently amended claims are believed to respond to this objection.

Claims 1, 19 and 24 stand rejected for including the limitation “referred to a surface area unit.” However, as discussed above, this feature is clear to a person skilled in the art and the claims have been amended to clarify this terminology.

The independent claims are rejected for including the limitations “on the one hand” and “on the other hand.” According to the claimed invention, both said digitized radiological data and a 3-dimensional generic model of the osseous body are used, so that the present claim amendments are believed to respond to this objection, as well to that of claim 12.

Action (b) of claim 2, (b') of claim 5, and the analogous limitations present in claim 20 are said to be unclear. The examiner refers to the excerpt “in the first incidence, each anatomical part comprising said osseous body and transmitted by each of the scanned parts, and delivering, ... signals corresponding to the radiation transmitted.” However, the examiner takes only a part of action (b) (now action (d)). According to the action: X-rays scan, in a first incidence, each anatomical part comprising the osseous body, and are transmitted by each of the scanned parts. The energy of the radiation corresponding to these X-rays is detected by virtue of detection means. Signals corresponding to the radiation transmitted are delivered from the detector. Thus, action (b) makes sense, as well as action (b') of claim 5 and claim 20.

Claims 9, 15, 11, 13, 17, 18 stand rejected for using “the.” The present amendment is believed to respond to this objection.

Claim 12 stands rejected for using “non stereo corresponding control markers.” The present claim amendment is believed to respond to this objection.

Claim 23 stands rejected for stating equations  $F_i$  and for stating “R in R.” However, claim 23 does not state equations “ $F_i$ .” The present amendments are believed to overcome the present rejection.

Claim 22 stands rejected for including the limitation “a detector comprising a line of detection cells perpendicular to the axis of translation.” This rejection has been addressed above.

Hence, it is respectfully submitted that the currently pending claim set complies with 35 USC §112. Therefore, applicants respectfully request withdrawal of the 35 USC §112 rejections.

Claim rejections under 35 USC §102

Claims 1 to 10 and 15 to 25 stand rejected under 35 USC §102(a) as being anticipated by WO 02/38045.

The applicant reserves any right to show that the invention was made before the date of publication of WO 02/38045, and thus that this document is not prior art under 35 USC §102(a).

According to the examiner, Charles would disclose a “storage device for storing at least one 3 dimensional generic model for the osseous body,” referring to Fig. 10, Fig. 3 :350-370, 390-398, Fig. 8 : 806-810.

However, Charles does not disclose any generic model.

According to freedictionary.com, “generic” means “relating to or descriptive of an entire group or class ; general.” In Charles, according to paragraph 0 01 01, located, page 32, between paragraphs 145 and 146, “cone beam reconstruction is employed to complete 3 dimensional model of the bone. It is anticipated that the cone beam reconstruction with from 3 to 7 projections is adequate to produce a pseudo 3D geometry which is mechanically equivalent to a measured hip. Fig. 9d is a sequence of seven images depicting a cone beam reconstruction used to construct a 3D model according to the actions of the method in Fig. 7.”

Hence, Charles does not use a 3D generic model of the osseous body as claimed.

Hence, Charles does not disclose action b of determining the value of a composite index using the digitized radiological data and a 3-dimensional generic model of the osseous body.

The use of a generic model, as claimed, enables to reduce the number of images necessary to calculate the composite index, which therefore, reduces the level of irradiation to which the patient is subjected. Further, the use of a generic model allows to improve the accuracy of the composite index, because the 3D model used by Charles, based only on few images, will not be very accurate.

Hence, the present invention enables the production of a very accurate composite index, furthermore by a method which reduces the irradiation to the patient. Accuracy of the composite index is essential, since a medical decision might be taken based on this composite index.

There is no hint to modify the method of Charles to improve the accuracy and reduce the level of irradiation of the patient by using a generic model, so that the claims are not obvious in view of Charles.

Claim rejections under 35 USC §103

Applicants respectfully traverse the rejection of 9-14, 16, and 23 under 35 USC §103(a) as unpatentable over Charles in view of Mitton as dependent claims 9-14 and 16 are dependent of claim 1 and claim 23 is dependent upon claim 19. As discussed above, claims 1 and 19 are believed to be allowable. Further, it is respectfully submitted that Mitton does not supply the claimed feature identified as deficient in Charles.

It is therefore respectfully requested that the rejection of claims 9-14, 16, and 23 under 35 USC §103(a) over Charles in view of Mitton be withdrawn.

**CONCLUSION**

In view of the above amendment and arguments, the applicant submits the pending application is in condition for allowance and an early action so indicating is respectfully requested. If there are matters that can be discussed by telephone to further the prosecution of this application, applicants respectfully request that the examiner call its attorneys at the number listed below.

The Commissioner is authorized to charge any fee deficiency required by this paper, or credit any overpayment, to Deposit Account No. 13-2855, under Order No. 28944/41376, from which the undersigned is authorized to draw.

July 31, 2009

Respectfully submitted,

By 

Milena Sukovic

Registration No.: 60,532

MARSHALL, GERSTEIN & BORUN LLP

233 S. Wacker Drive, Suite 6300

Willis Tower

Chicago, Illinois 60606-6357

(312) 474-6300

Attorney for Applicant